STATE OF MICHIGAN

IN THE SUPREME COURT

(ON APPEAL FROM THE MICHIGAN COURT OF APPEALS)
(Collins, P.J. (not participating), and Murphy and Jansen, JJ.)

TAMARA TAYLOR and LEE ANNE RINTZ,

Plaintiffs-Appellees,

v

MEDEVA PHARMACEUTICALS, INC.,

Defendant-Appellant,

and

GATE PHARMACEUTICALS,
SMITHKLINE BEECHAM CORPORATION,
A.H. ROBINS COMPANY, INC.,
WYETH-AYERST LABORATORIES COMPANY,
AMERICAN HOME PRODUCTS CORPORATION,
ZENITH GOLDLINE PHARMACEUTICALS, INC.,
ABANA PHARMACEUTICALS, INC.,
RICHWOOD PHARMACEUTICAL COMPANY, INC.,
ION LABORATORIES, INC.,
INTERNEURON PHARMACEUTICALS, INC.,
CAMALL COMPANY, LABORATORIES SERVIER,
AND ALL MICHIGAN PHYSICIANS WHO PRESCRIBED
OR GAVE FEN-PHEN AND/OR REDUX TO MICHIGAN PATIENTS,

Defendants.
/

S.C. Nos. 120642-45

C.A. Nos. 217269, 217279, 217290 and 217328 (consolidated)

DEFENDANT-APPELLANT MEDEVA PHARMACEUTICALS, INC.'S BRIEF ON APPEAL IN DOCKET NOS. 120642-45 (TAYLOR) AND 120646 (ROBARDS)

JUDITH H. ROBARDS and KENNETH W. ROBARDS,

Plaintiffs-Appellees,

v

MEDEVA PHARMACEUTICALS, INC.,

Defendant-Appellant,

S.C. No. 120646

C.A. No. 227700

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STATEMENT IDENTIFYING THE JUDGMENT APPEALED FROM AND INDICATING THE RELIEF SOUGHT

Defendant-Appellant Medeva Pharmaceuticals, Inc. ("Medeva") appeals from the November 30, 2001 published opinion of the Michigan Court of Appeals, in which that Court held unconstitutional MCL 600.2946(5); MSA 27A.2946(5), which provides that a drug is not dangerous and a manufacturer or seller is not liable if the drug was approved for safety and efficacy by the United States Food and Drug Administration (FDA). In its 2-0 ruling (Collins, P.J., not participating), the Court held that § 2946(5) operates as an unconstitutional delegation of legislative authority to the FDA (Apx 152a). This Court has jurisdiction to review and resolve the issue presented. MCR 7.301(2).

Medeva requests this Court reverse the order denying summary disposition in the *Taylor* case and reinstate the order granting summary disposition in *Robards*, together with all costs and attorneys' fees sustained on appeal.

STATEMENT OF THE QUESTION PRESENTED

I.

WHETHER MCL 600.2946(5); MSA 27A.2946(5), WHICH PROVIDES THAT THE MANUFACTURER OR SELLER OF A DRUG IS NOT LIABLE IF THAT DRUG WAS APPROVED FOR SAFETY AND EFFICACY BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION, IS CONSTITUTIONAL UNDER THE NONDELEGATION DOCTRINE?

Defendant-Appellant Medeva Pharmaceuticals Inc. says "yes."

Plaintiffs-Appellees say "no."

The trial court in *Taylor* says "no."

The trial court in *Robards* says "yes."

The Michigan Court of Appeals says "no."

STATEMENT OF FACTS

A. Introduction.

These are drug liability cases[1] in which the Plaintiffs[2] assert they were injured because of their use of the drugs fenfluramine, phentermine, and dexfenfluramine, which are FDA-approved prescription pharmaceuticals allegedly manufactured and/or distributed by the named Defendants, including Medeva. The Defendants requested summary disposition on the basis of MCL 600.2946(5); MSA 27A.2946(5), which provides in pertinent part:

> "In a product liability action against a manufacturer or seller, a product that is a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable, if the drug was approved for safety and efficacy by the United States food and drug administration . . . ."

In response, the Plaintiffs conceded the applicability of § 2946(5) to their cases, and conceded that none of the exceptions set forth in that statute applies to the instant controversy. Plaintiffs instead argued that § 2946(5) is unconstitutional on various grounds, including unconstitutional delegation of judicial and legislative power, denial of right of access to the courts, equal protection, and due process. In *Taylor*, the trial court rejected all but one of plaintiffs' constitutional challenges. In an opinion dated November 24, 1998, the trial court found that § 2946(5) is unconstitutional "because it

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[1] This type of litigation is sometimes known as "Fen-Phen", a phrase neither adopted by nor approved of by Medeva. The phrase is used here only for identification purposes.

[2] The claims of the *Taylor* and *Robards* Plaintiffs are identical for purposes of this appeal. Each set of Plaintiffs is represented by the same counsel. Each Plaintiff posed the same constitutional challenges in the lower courts.

improperly delegates to the FDA the legislative function of determining what is a cause of action." (Apx 119a-121a, 130a.) The trial court recognized that the issue presented is one of first impression, and stayed all further proceedings in the trial court pending an appellate determination of the constitutionality of § 2946(5). (Apx 133a.) Medeva, together with other defendants through separate applications, sought leave to appeal to the Michigan Court of Appeals on the constitutional question presented. The Court granted the applications through an order dated May 24, 1999 (Apx 138a-141a)

In *Robards*, the trial court rejected Plaintiffs' constitutional challenges. Plaintiffs appealed by leave granted on the constitutional questions presented. The Court granted the application through an order dated September 15, 2000 (Apx 142a). The Michigan Court of Appeals consolidated *Taylor* and *Robards* for argument and decision (138a-142a). In a 2-0 ruling, the Court held that § 2946(5) operates as an unconstitutional delegation of legislative authority to the FDA (Apx 143a).

B. Statement of material proceedings.

1. *Taylor.*

On October 2, 1997, Plaintiffs filed their original class action complaint and demand for jury trial with the Wayne County Circuit Court (Apx 4a). Plaintiffs amended by right and, on October 3, 1997, filed their amended class action complaint and demand for jury trial (Apx 5a). On October 7, 1997, Plaintiffs filed their second amended class action complaint for damages and medical monitoring and demand for trial by jury (Apx 6a. On October 23, 1997, plaintiffs filed their motion for certification of action as a class

action and accompanying documents (Apx 6a). In the following weeks, the respective defendants filed their answers, affirmative defenses, and jury demands (reliance on jury demands) (Apx 8a-15a). On May 6, 1998, Plaintiffs filed their second amended motion for certification of action as a class action (Apx 30a).

Through a series of meetings among counsel, it became apparent that Plaintiffs would challenge § 2946(5) as being unconstitutional and that Plaintiffs and defendants thought it advisable to have the courts of this state, including the appellate courts, determine this constitutional question before further consideration of the propriety of a class action and of the merits of the case.

On April 17, 1998, Co-Defendant American Home Products Corporation filed its motion for summary disposition and accompanying documents, in which it contended that § 2946(5) applied to this action, that none of the exceptions to that statute applied to this action, and that § 2946(5) required the grant of summary disposition in favor of the respective defendants (Apx 28a). The remaining Defendant manufacturers and/or distributors joined in that motion through formal joinders (Apx 29a-30a).

On May 29, 1998, Plaintiffs responded to the motion for summary disposition, in which they conceded that § 2946(5) applies and that none of the exceptions listed in the statute applies to this case (Apx 32a). Plaintiffs instead contended that § 2946(5) was unconstitutional on various grounds. The Defendants responded with various reply briefs (Apx 32a-34a).

On September 11, 1998, the trial court entertained oral argument on the motion for summary disposition (Apx 35a). During the course of that argument, the trial court

requested supplemental briefs on the question of separation of powers/delegation of legislative authority (Apx 230a). The parties filed the respective supplemental briefs on this point (Apx 39a-38a).

On November 24, 1998, the trial court issued its Opinion in which it rejected all but one of Plaintiffs' constitutional challenges. The trial court found that § 2946(5) is unconstitutional because it improperly delegates to the FDA the legislative function of determining what is a cause of action (Apx 119a-120a, 130a).

A conforming order was entered on January 8, 1999. In that order, the trial court stayed further proceedings at the trial court level, "pending an appellate determination of the constitutionality of the statute." (Apx 133a).

Within 21 days of entry of that order, Medeva filed its application for leave to appeal and accompanying documents, dated January 29, 1999. Other Defendants also filed applications for leave to appeal. The Michigan Court of Appeals granted the applications and consolidated the appeals through an order dated May 24, 1999 (Apx 138a-141a), and reversed in its Opinion dated November 30, 2001 (Apx 143a).

2. *Robards*

On October 14, 1999, Plaintiffs filed their original complaint and demand for jury trial with the Washtenaw County Circuit Court (Apx 55a). In the following weeks, the respective Defendants filed their answers, affirmative defenses, and jury demands (reliance on jury demands) (Apx 52a-54a).

Through a series of meetings among counsel in other Fen-Phen cases being prosecuted by Plaintiffs' attorneys, it became apparent that Plaintiffs would challenge § 2946(5) as being unconstitutional.

On December 14, 1999, Co-Defendant American Home Products Corporation filed its motion for summary disposition and accompanying documents, in which it contended that § 2946(5) applied to this action, that none of the exceptions to that statute applied to this action, and that § 2946(5) required the grant of summary disposition in favor of the respective Defendants (Apx 54a). The remaining Defendant manufacturers and/or distributors joined in that motion through formal joinders (Apx 51a-54a), including Medeva (joinder dated January 21, 2000) (Apx 51a).

On February 23, 2000, Plaintiffs responded to the motion for summary disposition, in which they conceded that § 2946(5) applies and that none of the exceptions listed in the statute applies to this case (Apx 51a). Plaintiffs instead argued that § 2946(5) was unconstitutional on various grounds.

On March 15, 2000, the trial court entertained oral argument on the motion for summary disposition (Apx 50a). The trial court ruled that § 2946(5) is constitutional.

A conforming order was entered on April 12, 2000 (Apx 135a).

On June 7, 2000, Plaintiffs filed their delayed application for leave to appeal and accompanying documents. On September 15, 2000, the Michigan Court of Appeals granted leave to appeal and consolidated *Robards* with *Taylor v Medeva*, Court of Appeals Docket Nos. 217269, 217279, 217290 and 217328 (Apx 142a). On November 30, 2001, the Court reversed and remanded (Apx 143a).

C. Statement of material facts.

The Defendants' motions for summary disposition were resolved by the respective trial courts under MCR 2.116(C)(10), which required the Defendants to assume for purposes of that motion the truth of the factual allegations set forth in Plaintiffs' complaints. Consistent with the procedural rubric by which the trial courts rendered their opinions and this Court now reviews the issues presented, Medeva likewise assumes *arguendo*, for purposes of this application only, that the factual allegations of Plaintiffs' complaints are true.[3]

Plaintiffs contend that they were prescribed and ingested the diet drugs fenfluramine, phentermine and dexfenfluramine, which were manufactured and/or distributed by various Defendants, including Medeva (Apx 159a; 178a-179a). Plaintiffs contend that physicians prescribed these pharmaceuticals to the Plaintiffs in excess of the recommended dosage period and otherwise failed to properly warn the Plaintiffs of dangerous medical side effects, including pulmonary hypertension (Apx 160a; 176a-177a). Plaintiffs further allege that the Defendant manufacturers/distributors failed to use due care in designing and manufacturing the pharmaceuticals to avoid risks when these drugs were being used for weight loss, and otherwise contend that these drugs were unreasonably dangerous (Apx 161a-162a; 178a-179a).

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[3] Medeva strongly denies most of the factual allegations set forth in Plaintiffs' complaints, as confirmed in Medeva's answers. Medeva does not concede the factual allegations on the merits, or for any other purpose in this litigation or otherwise.

In response to the Defendants' motion for summary disposition, Plaintiffs admitted that the drugs at issue were labeled in compliance with FDA requirements, and that the Plaintiffs had not pled any of the statutory exceptions to MCL 600.2946(5); MSA 27A.2946(5) (Apx 148a).

D. The trial courts' rulings.

1. *Taylor.*

In *Taylor*, the trial court agreed with only one of Plaintiffs' constitutional challenges. The trial court found that § 2946(5) improperly delegates to the FDA the legislative function of determining what is a cause of action, and is thus unconstitutional (Apx 130a). The trial court reasoned that the Michigan Legislature cannot make a determination of whether there is an actionable claim for a drug-related product liability action dependent on the finding of a federal agency (Apx 120a). "[I]f indeed it is legislative power to define what constitutes an actionable cause of action, then the legislature has effectively delegated this power to the FDA" (Apx 120a). The trial court ruled that § 2946(5) is therefore an unlawful delegation of legislative power to a federal agency (the FDA) to decide the safety and fitness of a particular drug, which is binding in a Michigan court (Apx 120a).

The trial court understood that its decision is one of first impression in Michigan and that appellate review is desired before there is any further activity in the trial court level (as reflected by the entry of the stay of proceedings pending decision on appeal) (Apx 133a).

2. ***Robards.***

In *Robards*, the trial court rejected Plaintiffs' constitutional challenges, reasoning that the statute is presumed constitutional, and Plaintiff failed to demonstrate otherwise (Apx 244a-245a). The trial court was aware that the constitutionality of § 2946(5) was being considered by the Michigan Court of Appeals in *Taylor*.

E. <u>The Michigan Court of Appeals opinion.</u>

In a 2-0 ruling dated November 30, 2001, the Michigan Court of Appeals panel (Murphy and Jansen, JJ.)[4] held that MCL 600.2946(5) operates as an unconstitutional delegation of legislative authority. The panel found that a nondelegation doctrine has been applied in Michigan through judicial interpretation, although the Michigan Constitution does not explicitly provide that legislative power cannot be delegated (Apx 149a). The panel examined case law and concluded that statutes which incorporate *existing* federal or sister state standards are valid and constitutional. The court held, however, that it is an unlawful delegation of legislative power to adopt by reference *future* legislation enacted by another sovereign entity (Apx 144a).

"Given these distinctions and parameters," the panel determined that § 2946(5) operates as an unconstitutional delegation of legislative authority:

> "It places the FDA in the position of final arbiter with respect to whether a particular drug may form the basis of a product liability action in Michigan. Regardless of the expertise the FDA possesses in the area of drug evaluation, specifically regarding safety and fitness determinations, this is

[4] Presiding Judge Collins did not participate, presumably because of his appointment by President Bush as the United States Attorney for the Eastern District of Michigan. This appointment was confirmed shortly before the issuance of the Court of Appeals opinion.

> unacceptable. Michigan retains no oversight of this federal agency, it cannot check the exercise of its delegated power with standards of any precision and, due to the nature of science and the FDA's processes of approval and withdrawal of the same, an ever evolving list of drugs will be excluded as bases of liability actions."

(Apx 152a).

The panel further rejected the Defendants' contention that § 2946(5) survives the nondelegation analysis under the doctrine of "independent significance." Defendants maintained that the Legislature simply adopted external FDA standards as its own and established the manner in which the legal consequences are to pertain to Michigan product liability law (Apx 152a). The panel found that assimilation of standards having independent significance presents no problems if the standards are established and essentially unchanging. However, in the case of FDA safety and efficacy determinations, a fatal problem exists since it is known at the onset that relevant features in the FDA process will be in constant flux (Apx 153a).

ARGUMENT I

MCL 600.2946(5); MSA 27A.2946(5), WHICH PROVIDES THAT THE MANUFACTURER OR SELLER OF A DRUG IS NOT LIABLE IF THAT DRUG WAS APPROVED FOR SAFETY AND EFFICACY BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION, IS CONSTITUTIONAL UNDER THE NONDELEGATION DOCTRINE.

A. Standard of review and supporting authority.

This Court reviews *de novo* both the question of constitutionality and the denial of a motion for summary disposition. *Toldsdorf v Griffith*, 464 Mich 1, 5; 626 NW2d 163 (2001); *Spiek v Dept of Transportation*, 456 Mich 331, 337; 572 NW2d 201 (1998). A statute is presumed to be constitutional, *Toldsdorf, supra*; *McDougall v Schanz*, 461 Mich 15; 597 NW2d 148, 153 (1999), and the burden is placed on the challenger to demonstrate otherwise. *Johnson v Harnischfeger Corp*, 414 Mich 102, 112; 323 NW2d 912 (1982); *Jeffrey Lauren Land Co v City of Livonia (On Remand),* 119 Mich App 682, 687; 326 NW2d 604 (1982). See also *Toldsdorf, supra*, 464 Mich at 5; *Clemons v City of Detroit,* 120 Mich App 363, 374-375; 327 NW2d 480 (1982) (the court has an obligation to strive to find a statute constitutional unless the contrary clearly appears).

B. Introduction-summary.

Section 2946(5) does not violate the nondelegation doctrine. The Michigan Legislature did not delegate to the FDA its power to make a law. The Michigan Legislature exercised its legislative responsibility by the very enactment of § 2946(5), through which the legislature decided on a policy basis that the independent scientific

judgments of government experts will govern the parameters of recovery in such a drug liability case. The Michigan Legislature may constitutionally delegate a power to determine some fact or state of things which, in turn, implements the legislative judgment reflected in a statute.

To the extent that § 2946(5) reflects a true delegation of a legislative power, it is lawful under the nondelegation doctrine for an administrative agency, such as the FDA, to "fill up the details" by prescribing administrative rules and regulations to promote the purpose and spirit of the legislation and to carry it into effect.

The Michigan courts have consistently recognized that the substantive requirements for prevailing in a tort action may be rendered dependent upon a status that is determined by a party other than the court and other than the Michigan Legislature.

C. MCL 600.2946(5); MSA 27A.2946(5).

Section 2946(5) provides:

> "(5) In a product liability action against a manufacturer or seller, *a product that is a drug is not defective or unreasonably dangerous*, and the *manufacturer or seller is not liable, if the drug was approved for safety and efficacy by the United States food and drug administration*, and the drug and its labeling were in compliance with the United States food and drug administration's approval at the time the drug left the control of the manufacturer or seller. However, this subsection does not apply to a drug that is sold in the United States after the effective date of an order of the United States food and drug administration to remove the drug from the market or to withdraw its approval. This subsection does not apply if the Defendant at any time before the event that allegedly caused the injury does any of the following:
>
> > (a) Intentionally withholds from or misrepresents to the United States food and drug administration information concerning the drug that is required to be submitted under the federal food, drug, and cosmetic act, chapter 675, 52 Stat.

> 1040, 21 U.S.C. 301 to 321, 331 to 343-2, 344 to 346a, 347, 348 to 353, 355 to 360, 360b to 376, and 378 to 395, and the drug would not have been approved, or the United States food and drug administration would have withdrawn approval for the drug if the information were accurately submitted.
>
> (b) Makes an illegal payment to an official or employee of the United States food and drug administration for the purpose of securing or maintaining approval of the drug."

(Emphasis supplied).

Plaintiffs conceded the statute applies to the drugs at issue. Plaintiffs further concede that none of the exceptions applies here.

Section 2946(5) is one component of Michigan legislation governing product liability actions. In 1995, the Michigan Legislature reviewed the product liability statute that existed at that time, former MCL 600.2945; MSA 27A.2945, as a part of overall tort reform in Michigan. Legislators in both the Michigan House of Representatives and the Michigan Senate studied proposed legislation, debated the current tort provisions governing product liability litigation, and ultimately revised Michigan's product liability scheme. Part of that revision is § 2946(5), which has particular application and importance in the context of drug liability litigation.

The Michigan Legislature engaged in broad policy deliberations when it considered the arguments for and against § 2946(5). The legislative history of the statute notes the apparent concerns addressed by the statute, as well as the considerations weighed by the Legislature. After noting criticisms of the then-current tort system (among others, that the system stifled innovation, restricted the availability of goods and

services, and reduced the competitiveness of Michigan business, leaving the "look of a lottery"), a House analysis report states:

> ". . . Critics [of the tort system] claim that defendants are sometimes victims of "junk science" – theories of causation propagated by professional expert witnesses outside the scientific mainstream but convincing to juries of ordinary citizens . . . The uncertainty and fear that surround the arena of product liability inhibits the development and introduction of new products, critics say, including products with great utility in the prevention of illness and disease."

House Legislative Analysis Section Report on Senate Bill 344 (H6), First Analysis dated 6/8/95 at 1 (emphasis added). With respect to the language of § 2946(5) specifically, the Report states that:

> ". . . The [House substitute bill] does contain the absolute defense language for a manufacturer or seller of drugs that are FDA-approved.
>
> . . . The bill says, moreover, that drug companies whose products receive FDA approval for safety and effectiveness are not liable unless the company deceived the government in the approval process. Drug companies spend large sums of money and expend enormous energy getting approval of their products. Many valuable products never reach the market or are withdrawn because of successful lawsuit (or the threat of future lawsuits) even though there is no medical evidence that they are harmful . . . ."

(*Id* at pp 8-10). In similar fashion, a Senate bill analysis notes that:

> ". . . According to many, over the past several years there has been an explosion of product liability litigation, *resulting in unfair and excessive judgments against manufacturers and sellers, bankruptcies, reduced capacity of firms to compete internationally, curtailed innovation, reduced funding for research, higher consumer costs, and unaffordable or unavailable casualty insurance.*
>
> * * *
>
> [According to supporting arguments] The bill would do a great deal to address the excess of tort law, especially in the product liability field.

> According to an article in *Business Week*, 'Each year, over $100 billion flows through the liability system from companies to lawyers and claimants' (7/29/91). In addition to paying the direct costs of lawsuits, damages awards, and insurance premiums, businesses and *the economy suffer incalculable costs when products cannot be developed or marketed due to potential litigation.* Small business and innovation are especially hard-hit within this internationally competitive environment, especially when a firm is forced to choose between not marketing a product and risking bankruptcy because insurance is not available. *Consumers, too, suffer when they are denied new products that would increase public safety or improve their quality of life, or when existing products are discontinued, prices are raised, and jobs are lost.* Unfortunately, manufacturers often are considered impersonal, rich, and even greedy, which makes them an easy target for product liability claims. *As a result, product liability litigation not only has threatened the financial viability of many enterprises, but also has added substantially to the cost and unavailability of many goods and services.* The bill would reverse this trend by significantly limiting manufacturers' and sellers' exposure to liability and encouraging early settlements.
>
> * * *
>
> It is unfair to deem a product defective when it conforms to all government standards, especially if the product has been tested under the oversight of a Federal or state agency. These standards are promulgated after intense public scrutiny, expert evaluation, and thorough product evaluation. Lay jurors should not be allowed to second-guess a standard that has been developed by government experts. . . ."

Senate Fiscal Agency Bill Analysis on Senate Bill 344, Date Completed: 8/28/95 at 1, 9-10 (emphasis added).

The Michigan Legislature performed its policy function of defining the parameters of a tort action when debating and ultimately enacting § 2946(5). This is true legislative power. The nondelegation doctrine is not violated by reference to a federal agency's processes and determination by which the dangerousness of a pharmaceutical is measured.

D. Argument.

The Plaintiffs' nondelegation argument is fatally flawed for two principal reasons: (1) the Michigan Legislature did not delegate legislative powers in a constitutional sense through enacting § 2946(5), and; (2) assuming *arguendo* there is a delegation of legislative power, it is authorized by the nondelegation doctrine and is otherwise constitutional.

To assist the Court in placing these arguments in context, Medeva first provides the following summary of the nondelegation doctrine and its narrow boundaries.

1. Separation of powers: the nondelegation doctrine.

The separation of powers principles which underlie the United States Constitution, and by analogy the Michigan Constitution,[5] simultaneously limit and protect legislative

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[5] The relevant provisions of the Michigan Constitution are:

Const 1963, art 3, § 2:

> "The powers of argument are divided into three branches: legislative, executive and judicial. No person exercising powers of one branch shall exercise powers properly belonging to another branch except as expressly provided in this constitution,"

Const 1963, art 6, § 1:

> "The judicial power of the state is vested exclusivity in one court of justice which shall be divided into one supreme court, one court of appeals, one trial court of general jurisdiction known as the circuit court, one probate court, and courts of limited jurisdiction that the legislature may establish by a two-thirds vote of the members elected to and serving in each house,"

Const 1963, art 6, § 5:

power. The primary separation of powers *limitation,* apart from the limits which constrain legislative usurpation of judicial or executive authority, is known as the nondelegation doctrine. Tribe, *American Constitutional Law,* Section 5.17 (2nd Ed 1988).

Delegation may take the form of either interstitial administrative action or of contingent legislation. In the former case, Congress, and by analogy the Michigan Legislature, may grant authority to an administrative agency to specify rules in areas where Congress itself has only declared general principles. In the latter case, Congress may condition the operation of legislation upon an administrative agency's official determination of certain facts. These forms of delegation are not mutually exclusive. In most modern instances of delegation by Congress, there is contingent legislation in interstitial administrative actions. See, e.g., *FEA v Algonquin SNG, Inc,* 426 US 548 (1976) (court upholds delegation of authority to President to adjust imports of which quantities or circumstances may be threatening to national security).

The fundamental precept of the nondelegation doctrine is that lawmaking function belongs to the Legislature, and may not be abandoned. *Field v Clark*, 143 US 649, 692; 12 S Ct 495, 504; 36 L Ed 294 (1892). However, the United States Supreme Court

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> "The supreme court shall by general rules establish, modify, amend and simplify the practice and procedure in all courts of this state. The distinctions between law and equity proceedings shall, as far as practicable, be abolished. The office of master in chancery is prohibited," and

Const 1963, art 4, § 1:

> "The legislature power of the State of Michigan is vested in a senate and a house of representatives."

established long ago that Congress, and by analogy the Michigan Legislature, must be permitted to delegate to others some authority that itself could exercise. *Wayman v Southard*, 10 Wheat 1, 42; 6 L Ed 253 (1825). To burden the legislative branch with all rulemaking would divert this branch of government from more pressing issues. *ALA Schechter Poultry Corp v United States*, 295 US 495, 529-530; 55 S Ct 837; 79 L Ed 1570 (1935); 5 Works of Thomas Jefferson 319 (P Ford ed 1904) (Letter to E. Carrington, August 4, 1787).

Given the basic structure of government in the State of Michigan, certain legislative powers are simply not delegable. *People v Turmon,* 417 Mich 638, 625-626, 649; 340 NW2d 620 (1983).[6] In such cases, the nature of the function within the constitutional framework of the government precludes delegation. *Turmon, supra,* 417 Mich at 649.

Delegation of legislative power is scrutinized more carefully in certain areas, such as special legislation for the protection of individual human rights and liberty interests, delegation to special-interest groups which may tend to perpetuate their own self interests rather than the common good, and delegation to administrative agencies to define or create crimes. *Legislation – Procedure and Interpretation,* 45 La Law Rev 341, 351-354 (1984). *See also Turmon, supra,* 417 Mich at 649-450 (creation of crimes is an

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[6] For example, certain powers of the legislative branch require exercise by the Senate or the House of Representatives, or both, in order for their purposes to be served. *See* Const 1963, art 11, § 7, which grants to the House of Representatives the power to impeach civil officers and to prosecute impeachment. See generally *People v Turmon, supra*, 417 Mich at 625-626.

inherently legislative task); *Greene v McElroy,* 360 US 474, 507 (1959) (Court rejects finding of implicit congressional delegation of authority to the Department of Defense to administer a constitutionally questionable security clearance program); *Larkin v Grendel's Den, Inc,* 459 US 116 (1982) (Court strikes down Massachusetts law that allowed each church to prevent issuance of liquor licenses within a 500 foot radius of the church, reasoning that legislative duties could not be delegated to or shared with religious institutions).

In contrast, judicial scrutiny is less strict in areas of public health, safety and morals. Legislatures have been given broad discretion in dealing with such problems, which in turn may require more detailed supervision than a legislature can give, and may indeed sometimes require immediate action. Therefore, it is not uncommon to find much of the legislative authority in such areas delegated to administrative agencies. *Legislation – Procedure and Interpretation, supra,* 45 La Law Rev at 351. See also *Johnson v Pearce,* 313 So2d 812 (La 1975) (upholding regulations concerning eradication of brucellosis disease among animals).

Although this Court has addressed the nondelegation doctrine in several cases through the years, its parameters are less than clear, and its application is extremely infrequent. For example, at the United States Supreme Court level, that Court both first and last used the nondelegation doctrine to invalidate a federal statute in 1935.[7] In the decades since 1935, nondelegation challenges have been routinely repudiated in the

[7] *Panama Refining Co v Ryan*, 293 US 388 (1935). See also *ALA Schechter Poultry Co v United States*, 295 US 495 (1935).

United States Supreme Court.[8] The confluence of the infrequent use of the nondelegation doctrine and the invalidation of a critical piece of Michigan tort reform legislation requires a careful and critical review of the Michigan Court of Appeals' use of the doctrine to invalidate a substantive decision of the Michigan Legislature.

2. The Michigan Legislature did not delegate legislative powers in a constitutional sense when enacting MCL 600.2946(5); MSA 27A.2946(5).

Plaintiffs complain that the Michigan Legislature violated the separation of powers doctrine because the Legislature delegated to the FDA the power to determine whether or not a drug is defective and unreasonably dangerous.[9] To properly invoke the nondelegation doctrine, Plaintiffs must first demonstrate that § 2946(5) is a delegation of legislative power. It is not. There is no shirking of legislative responsibility by the mere reference to a federal administrative agency's finding which defines the parameters of the tort action.

The legal definition of "power" is "[t]he right, ability, authority or faculty of doing something . . . the authority to do any act which the grantor might himself lawfully perform." *Black's Law Dictionary* (5th Ed 1979). "Delegation of power" means the

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[8] See *Mistretta v United States*, 488 US 361 (1989); *Lichter v United States*, 334 US 742 (1948); *Yakus v United States*, 321 US 414 (1944).

[9] This is an inaccurate description of § 2946(5) because the Michigan Legislature itself determined the level of safety and efficiency for tort purposes, namely FDA approval. The FDA, as supposed delegate, does not balance competing scientific, social or political considerations to determine then whether a tort claimant may prevail in a Michigan-based lawsuit. On the contrary, the FDA approval process is independent from the goal and policymaking decisions retained by the Michigan Legislature.

"[t]ransfer of authority by one branch of government in which such authority is vested in some other branch or administrative agency" (*Id*). Section 2946(5) does not involve the delegation of legislative power to an administrative branch of government. "The power to ascertain facts, which automatically brings a law into operation by virtue of its own terms, is not the power to pass, modify, or annul a law." *State v King*, 257 NW2d 693, 697 (Minn 1977) quoting with approval *Lee v Delmont*, 36 NW2d 530, 538 (Minn 1949). The FDA does not have the authority to decide which Plaintiff in a Michigan court (or in cases in which Michigan substantive laws applies) may prevail in a lawsuit. The Michigan Legislature itself made this policy determination through the exercise of its judgment and by the very enactment of § 2946(5).

It is one thing for a legislature to delegate its power to make the law. It is an entirely different matter when a legislature exercises its governmental function by referencing a federal administration's processes and findings to define the parameters of a cause of action which the Legislature itself can define. This distinction was made years ago by the United States Supreme Court in *Field v Clark, supra,* 143 US at 694 (1892):

> "The legislature cannot delegate its power to make a law, but it can make a law to delegate a power to determine some fact or state of things upon which the law makes, or intends to make, its own action depend. To deny this would be to stop the wheels of government. There are many things upon which wise and useful legislation may depend which cannot be known to the law-making power, and must therefore be a subject of inquiry and determination outside of the halls of legislation."

Quoted with approval in *State v Thompson,* 627 SW2d 298, 303 (Mo 1982) (en banc).

Section 2946(5) is no different than when a legislature constitutionally authorizes an administrative body to determine those facts that will make a statute effective. This is not the delegation of legislative authority:

> "The power to ascertain facts, which automatically brings a law into operation by virtue of its own terms, is not the power to pass, modify or annul a law. If the law furnishes a reasonably clear policy or standard of action which controls and guides the administrative officers in ascertaining the operative facts to which the law applies, . . . the discretionary power delegated to the board or commission is not legislative."

State v King, 257 NW2d 693, 697 (Minn 1977) (Legislature not prevented from delegating authority to Board of Pharmacy to revise statutory schedules enumerating controlled substances, including phentermine).

Plaintiffs' separation of powers argument is premised upon the false notion that the Michigan Legislature has delegated legislative responsibilities to the FDA. The impression given by Plaintiffs is that the Michigan Legislature left it to the FDA to issue tort policy in Michigan. To the contrary, the responsibility to set policy is firmly retained by the Michigan Legislature, and is not cloaked upon the FDA. The statute in question does not provide that the FDA will decide who can and cannot prevail in a product liability action in Michigan. That power is reserved for the Michigan Legislature. It is crucial to understand this point. The Michigan Legislature could have left to the FDA the task to determine whether prescription drugs which obtain approval can be challenged as unreasonably dangerous or defective for tort purposes. It did not delegate this goal making power, but instead decided as a matter of policy that a certain level of acceptance in the scientific community - reflected by FDA approval - constitutes a threshold over

which a tort litigant may not recover against a manufacturer or seller. Section 2946(5) reflects a legislative determination that it is unfair to deem a product defective when it conforms to all government standards, and that lay jurors should not be allowed to second-guess a standard that has been developed by government experts. Senate Fiscal Agency Bill Analysis, SB 344 and HB 4508. *Id.* Section 2946(5) serves to minimize the stifling of product innovation, by which many valuable products never reach the market because of a successful lawsuit (or threat of future lawsuits), absent medical evidence that such product is harmful. The legislative history shows an intent to defer to the science surrounding prescription drugs, as verified through the FDA approval process.

Court after court has recognized the constitutional ability of a legislative body to reference standards and determinations of technical and scientific experts which have an independent purpose to make findings in their specialized areas, which are then used by the legislative body to further the health and safety of the public. See, e.g., *Lucas v Maine Comm'n of Pharmacy*, 472 A2d 904, 911 (Me 1984) (court holds as proper a requirement that pharmacist be a graduate of a professional organization's accredited school); *State v Wakeen*, 57 NW2d 364 (Wis 1953) (definition of "drug" in official United States publication properly referenced in state statute regulating the sale of pharmaceuticals).

Plaintiffs' position runs contrary to cases such as *Madrid v St Joseph Hosp,* 928 P2d 250 (NM 1996). In *Madrid,* the court held as constitutional under the nondelegation doctrine the Legislature's decision to reference standards of private organizations into a statutory scheme. Specifically, the Legislature required mandatory reference to the

American Medical Association Guide to determine in the workers' compensation setting the existence of an impairment. Two workers challenged the provision under the nondelegation doctrine. The court held that the mere reference to a *private* standard does not constitute a delegation of legislative authority:

> "When a legislature adopts the standards of a private organization into a statutory scheme, as did our Legislature in Section 24, the incorporation is not always a delegation of legislative power. We find no delegation of legislative power in Section 24. Although the issue is one of first impression in New Mexico, many jurisdictions have articulated compelling rationales for allowing adoption of a private organization's standards into a statutory scheme without finding a delegation of legislative authority. This is true even when the standards are subject to periodic revision by the private entity."

928 P2d at 256. If reference to *private* standards does not violate the nondelegation doctrine, it necessarily follows that reference to a *federal agency's* guidelines is proper and constitutional.[10]

Madrid also stands for the proposition that use of outside standards that have significance independent of the legislative enactment are properly used without violating the nondelegation doctrine. 928 P2d at 257.

Plaintiffs' principal case law authority consists of two cases, *Coffman v State Board of Examiners in Optometry*, 331 Mich 582; 50 NW2d 322 (1951), and *Colony Town Club v Michigan Unemployment Compensation Comm'n*, 301 Mich 107; 3 NW2d 28 (1942). The Michigan Court of Appeals cited each case in its opinion.

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[10] In the lower court, Plaintiff questioned the adequacy of the FDA approval process, and suggested such inadequacy supports the notion that § 2946(5) is an unconstitutional delegation of power. Medeva counters that such questioning is immaterial. The critical question here is what powers, if any, are delegated.

In *Coffman, supra*, this Court held that the Michigan Legislature could not delegate to the International Association of Board Examiners in Optometry the rating of optometric schools or colleges. The rating function was established by statute and thus was the purview of legislation. In *Coffman,* the International Association of Board of Examiners adopted a ratings schedule contrary to that *specifically* set forth by statute, which was thus constitutionally offensive. This is a far cry from § 2946(5), through which the Michigan Legislature affirmatively adopted FDA approval for safety and efficacy as the threshold for whether a drug is defective or unreasonably dangerous. This result is contemplated, not rejected, by *Coffman*. The *Coffman* Court expressly acknowledged the "right to allow an administrative agency to adopt rules and regulations to effectuate purposes of the legislation." *Coffman,* 331 Mich at 325. This is exactly what the Michigan Legislature has done through § 2946(5). FDA approval is used merely as a frame of reference to determine when a substantive cause of action will be allowed. The Michigan Legislature retains the ability to change the criteria at any time. The Michigan Legislature could expand the parameters of § 2946(5), could narrow the scope of the statute, or could altogether revoke reference to FDA approval for determination of safety and efficacy of a drug. *McDougall, supra*, 597 NW2d at 158-159 (Legislature is authorized to change a common-law cause of action or abolish it altogether). No "power" has been "delegated," let alone a decision process which is retained exclusively and separately by the Michigan Legislature. *Coffman* therefore does

not support Plaintiffs' position or the Michigan Court of Appeals' determination that delegation to foreign agencies violates the nondelegation doctrine (Slip Op, p 9).[11]

In *Colony Town Club, supra*, this Court examined whether a federal agency's interpretation of a federal statute was binding on a Michigan court applying an identically worded Michigan statute. In the course of the opinion, this Court posed a hypothetical question on whether a statute would be constitutional if given a meaning that was not the meaning intended by the Michigan Legislature. In the context of that hypothetical, this Court opined that the nondelegation doctrine would be violated by the meaning which the Court hypothetically discussed. Any statement from this Court with respect to a hypothetical lacks the force of an adjudication, and is thus dicta. See, e.g., *Hett v Duffy*, 346 Mich 556; 78 NW2d 284 (1956); *People v Case*, 220 Mich 379; 190 NW 289 (1922) (statements in an opinion concerning some rule of law, however illuminating, are, when not necessary to decision of the case, but dicta, and lack the force of an adjudication). Finally, even if the hypothetical conclusion in *Colony Town Club* has force of law, it is distinguishable from this case since the hypothetical did not deal with the assimilation of an act of independent significance – namely an FDA determination – into a Michigan statute.

In conclusion, § 2946(5) reflects a legislative determination that the FDA can and will work more contemporaneously and efficiently than the Michigan Legislature itself when determining the safety of drugs from a tort perspective. Legislative power thus

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[11] Plaintiffs rely upon dictum in *Coffman* which referred to a Michigan Attorney General opinion unrelated to the issue presented and conceded by the *Coffman* parties.

exercised is not delegated in a constitutional sense. On the contrary, the Michigan Legislature made the fundamental legislative policy determination that potential dangers and efficacy associated with a particular drug are better analyzed by the FDA, with its administrative and technical expertise -- expertise that the individual legislators cannot be expected to possess. *People v O'Neal*, 122 Mich App 370, 376; 333 NW2d 56 (1983). This is the exercise of legislative power, not the abrogation of it.

There has been no "legislative power" delegated to the FDA. Rather, the Michigan Legislature has simply referenced the safeguards and protocols of the FDA process when defining the parameters of the tort action. The Michigan Legislature can always amend or rescind this provision. The Michigan Legislature can add to or eliminate the exceptions to § 2946(5). The FDA simply does not define the cause of action.

Absent the delegation of legislative power from the Michigan Legislature, Plaintiffs' nondelegation argument does not withstand scrutiny.

3. Assuming *arguendo* there is the delegation of legislative power, it is authorized by the nondelegation doctrine and otherwise constitutional.

Assuming for purposes of argument that there has been a delegation of legislative power, such a delegation is not violative of the nondelegation doctrine of the separation of powers provision. When analyzing this question, the first step is to determine the degree of scrutiny to be employed by the Court. Defining the parameters of the tort action is not an inherent legislative function that is non-delegable (such as the improper delegation of functions specifically set forth by constitution, *e.g.*, impeachment, *see*

footnote 5, *supra*). Nor is there a delegation of authority to a private or religious party. Finally, there is no delegation involving a liberty interest (as would be the case if, for example, a private body were defining the elements of a crime). On the contrary, tort law involves the health, safety and morals of the public. The Court should therefore be deferential to the delegation allegedly involved here.

Section 2946(5) reflects the Michigan Legislature's policy decision that the FDA's findings as to the safety and efficacy of a drug will be used in a tort action to determine whether a drug is unreasonably dangerous or defective, subject to exceptions which Plaintiffs concede are inapplicable here. The nondelegation doctrine is not violated "if the Legislature makes the fundamental policy decisions and leaves to some other body, public or private, the task of achieving the goals envisioned by the legislation." *People ex rel Younger v County of El Dorado,* 487 P2d 1193 (Cal 1971). The use of a federal agency's determination, assuming it is a "delegation," does not violate the nondelegation doctrine because the fundamental legislative policy decisions have not been delegated. This very point was recognized in *People v Valenti,* 153 Cal App 3d Supp 35; 200 Cal Rptr 862, 864 (1984):

> "Each of these sections evidences an overall legislative regulatory plan which, in part, incorporates reference to federal law to regulate and, where appropriate, punish unlawful aviation practices. We hold, therefore, that to the extent that reference to federal law is a "delegation" it is lawful under the doctrine that only the details of the task for achieving the goal and not the fundamental legislative policy have been delegated."

The Michigan courts recognize that reference to an administrative agency's determination is a permissible delegation of legislative power. As noted in *Penn School*

Dist No 7 v Board of Education of Lewis-Cass Intermediate School Dist, 14 Mich App 109, 122; 165 NW2d 464 (1969):

> "A legislative body may, after declaring a policy in fixing a primary standard, confer upon executive or administrative officers the 'power to fill up the details' by prescribing administrative rules and regulations to promote the purpose and spirit of the legislation and to carry it into effect; and the action of legislature in giving such rules and regulations the force and effect of laws does not violate the constitutional inhibition against delegating the legislative function."

Case law from this Court leaves no doubt that reference statutes are proper under the nondelegation doctrine:

> "Statutes which refer to other statutes and make them applicable to the subject of the legislation are called 'reference statutes.' Their object is to incorporate into the act of which they are a part the provisions of other statutes by reference and adoption. Reference statutes are of frequent use to avoid encumbering the statute books by unnecessary repetition, and they have frequently been recognized as an approved method of legislation, in the absence of constitutional restrictions."

City of Pleasant Ridge v Romney, 382 Mich 225, 246; 169 NW2d 625 (1969) (held that statute providing for arbitration of disputes involving determination of routes for interstate highways through municipalities, which incorporates by reference *federal* statutes, did not improperly delegate legislative power), quoting with approval *State v Rasmussen,* 128 P2d 318, 320 (Wash 1942).

If, as Plaintiffs apparently contend, the Michigan Legislature must set forth point by point the threshold of efficacy and safety for each pharmaceutical, the legislative process would be relegated to an unworkable regulatory process, in which the legislative body would not be devoting sufficient time and effort to, and constitutional observance of, the policy decisions behind legislation. "The legislature is not constantly in session,

and, therefore, even if its members were all trained chemists and pharmacists, it is impossible for them to keep abreast of the constantly changing drugs and medications and their inherent dangers." *State v Thompson*, 627 SW2d 298, 303 (Mo 1982) (en banc). Thus, it is generally recognized that in the delegation of administrative authority, a legislature may establish standards of a broad and general character:

> "If the Legislature were required to specify minutely and in detail the course to be pursued by the administrative agency and the acts which it might perform in the execution of the law, there would be little or no advantage gained by delegating even the administrative details. If the legislature were held to such strict requirements, it would in many instances be wholly impotent to provide workable legislation on a subject admittedly within the scope of its regulatory powers. As pointed out by the Supreme Court [*Mutual Film Corp v Industrial Commission* (1915), 236 US 230 (35 S Ct 387, 59 L Ed 552)] too much effort to detail and particularize, so as to dispense with the administrative or fact-finding assistance, would cause great confusion in the laws, and would result in laws deficient in both provision and execution."

Penn School Dist No 7, supra, 14 Mich App at 123-124.

Many Michigan statutes use reference or definition by status. Consider, *e.g.* MCL 500.3135(2)(c); MSA 24.3135(2)(c), which makes the question of liability for a motor vehicle accident dependent on whether the operator had "in effect for that motor vehicle the security required by [MCL] section 3101 at the time the injury occurred." Under this law, the extent of liability is directly attributable to the status of instrumentality claimed to be caused by the injury. In turn that status is not defined by courts, but rather defined by a private party, namely a liability carrier.

Also consider MCL 29.401; MSA 9.2101, which provides that tort damages do not lie for ordinary negligence by an instructor certified, assigned, approved, or contracted by

the Michigan firefighters' training council to provide instructional services.[12] There is nothing unusual or improper about a statute that requires for implementation some exercise of judgment by an institution other than the Legislature or a court.

Traffic statutes would be eviscerated under Plaintiffs' understanding of the nondelegation doctrine. MCL 257.301; MSA 9.2001, prohibits the driving of a motor vehicle without a license. Out-of-state licenses are honored, and those licenses are determined by an authority other than the Michigan Legislature, and other than the courts. Yet surely MCL 257.301 is not violative of the nondelegation doctrine. See also MCL 257.301(a); MSA 9.2001(a) (driving with a permit issued by the federal military authorities is a defense from liability under the statute which prohibits driving a motor vehicle without a valid license).

If, as Plaintiffs contend, reference is prohibited, then how could various industrial standards ever be incorporated into legislation (such as BOCA[13] and ASTM[14] standards)? When legislatures decide to reference such matters, the policy decision is made up front.

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[12] See also MCL 29.412; MSA 4.560(32), which provides the same rule for an institution of higher education, health facility, or an employee of such an institution or facility that participates in a training or educational practice approved by the Michigan firefighters' training council.

[13] See, e.g. MCL 125.1513c(2); MSA 5.2949(13c) (requiring a board and room facility to comply to the standards of the building officials and Code Administrators National Building Code ("BOCA") 1993 national property maintenance code). See also MCL 125.1504; MSA 5.2949(4), which provides that nationally-recognized model building codes shall be incorporated into the state construction code.

[14] See, e.g. MCL 324.21303; MSA 13A.21303 (adopting American Society for Testing and Materials ("ASTM") standards for corrective action of petroleum release sites).

There is no unlawful delegation of the policy-making process to the administrative agency itself.

Section 2946(5) provides quite simply that there is a finding that a drug is not unreasonably dangerous or defective upon the happening of a federal event, namely FDA approval of the drug in question. Case law makes clear that a legislature can so enact a statute without violating the nondelegation doctrine:

> "While the Legislature cannot delegate its lawmaking powers, it can make laws which 'become operative on the happening of a certain contingency or on an ascertainment of a fact upon which the law intends to make its own action depend.'"

Fulmer v Gensen, 379 NW2d 736, 740 (Neb 1986).

By analogy, consider those jurisdictions in which there is state legislation which references a federal statutory provision. This commonly occurs in the context of controlled substances, in which a stricter scrutiny is used to analyze whether there is an improper and unconstitutional delegation, given the liberty interest involved and the notion that legislatures cannot delegate their inherent powers to define a crime. Even in these cases, a majority of jurisdictions has found it permissible under the nondelegation doctrine for a state legislature to reference a federal statutory provision. See *People v O'Neal,* 122 Mich App 370, 377-378; 333 NW2d 56 (1983), in which the Michigan Court of Appeals acknowledges that courts in most jurisdictions have upheld such delegation.[15] See also *Apple v City and County of Denver,* 390 P2d 91; 154 Colo 166

[15] See *Ex parte McCurley,* 390 So2d 25 (Ala 1980) *on remand* 390 So2d 31 (1980); *Ward v State,* 248 Ga 60; 281 SE2d 503 (1981); *State v Kellogg,* 98 Idaho 541; 568 P2d 514 (1977); *Samson v State,* 27 Md App 326; 341 A2d 817 (1975); *State v Boyajian,* 344 A2d

(1964) ("[i]ncorporating into a statute the provisions of other statutes by reference is recognized as a proper enactment of legislation to avoid encumbering the statute books by unnecessary petition"); *Pennsylvania Medical Care Providers Assoc v Foster,* 613 A2d 51, 54 (Pa 1992) (held that general assembly's decision to incorporate a federal statute defining the Medicare reimbursement rates as the basis for calculating reimbursement to providers is a legitimate exercise of legislative function and not violative of the nondelegation doctrine).

If the courts find that reference is permissible for delegation purposes in the *criminal* law context (which requires a heightened degree of scrutiny when reviewed by the courts), it follows that reference in the *civil* context is certainly permissible under the nondelegation doctrine, given the deference to be afforded by the Court.

E. <u>The Michigan Court of Appeals' reasoning is flawed</u>.

The Michigan Court of Appeals panel held that § 2946(5) places the FDA in the position of final arbiter with respect to whether a particular drug may form the basis of a product liability action in Michigan (Slip Op, p 10). Noting that Michigan retains no oversight over the FDA, the panel reasoned that the Michigan Legislature "cannot check the exercise of its delegated power with standards of any precision." *Id.* As a result, the panel reasoned that there would be an ever evolving list of drugs excluded as the basis of

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410 (Me 1975); *State v King,* 257 NW2d 693 (Minn 1977); *State v Thompson,* 627 SW2d 298 (Mo 1982); *State v Lisk,* 21 NC App 474; 204 SE2d 868 (1974); *Montoya v O'Toole,* 94 NM 303; 610 P2d 190 (1980); *People v Einhorn,* 75 Misc2d 183; 346 NYS2d 986 (1973); *State v Sargent,* 252 Or 579; 449 P2d 845 (1969); *State v Peloquin,* 427 A2d 1327 (RI 1981); *State v Edwards,* 572 SW2d 917 (Tenn 1978); *Threlkeld v State,* 558 SW2d 472 (Tex Cr App 1977).

liability action dependent on the nature of the science and the FDA's processes of approval and withdrawal of same – without oversight of the Michigan Legislature. *Id.* Accordingly, § 2946(5) was found as an unconstitutional delegation of legislative authority. *Id.*

This reasoning is flawed on at least three grounds.

First, the Michigan Court of Appeals panel failed to properly define what constitutes legislative power with respect to § 2946(5) and, following that, to determine whether that legislative power has been delegated by the statute. The policy questions which underlie the enactment of § 2946(5) are evident from the legislative history:

- Did the then-current tort system stifle innovation, restrict availability of goods and services, and reduce competitiveness of Michigan businesses, leaving the "look of a lottery"?
- Were Defendants becoming victims of "junk science" – theories of causation propagated by professional expert witnesses outside the scientific mainstream, but convincing to juries of ordinary citizens?
- Did potentially valuable scientific products fail to reach the market because of successful lawsuits (or threats of future lawsuits), absent medical evidence that such a product is or could be harmful?
- Is it fair to deem a product defective when it conforms to all government standards – especially exacting FDA standards?
- Whether lay jurors should be allowed to second guess a standard that has been developed by specially-trained and experienced government experts? and
- Should the Legislature defer to the science surrounding prescription drugs, as verified through the FDA approval process, when determining defenses to and the scope of allowable recovery in a drug liability action?

Each of these matters was considered by the Michigan Legislature when it evaluated, debated and enacted § 2946(5). Each of these factors relates to tort policy in Michigan regarding drug liability actions. Through its decisions on these policy questions, the Michigan Legislature decided the policy matters which surround this area. There is no delegation of *legislative* duties and responsibilities to the alleged delegate – the FDA. On the contrary, the FDA does not make its determination for purposes of the Michigan legislation, but rather for an independent reason, as charged by Congress.

The Michigan Court of Appeals panel misunderstood and thus misapplied the scope of the nondelegation doctrine. That doctrine arises from the limitation on the Legislature's power to delegate the power of legislation to others, including to other branches of government and nongovernment. Const 1963, art 3, § 2; US Const, art 1, § 1. Unchecked delegation of the power to legislate undercuts the Legislature's accountability to the electorate, and subjects the populous to rule through ad hoc commands rather than democratically considered general laws. *ALA Schechter Poultry Corp, supra*; *Industrial Union Dept, AFL-CIO v American Petroleum Inst*, 448 US 607, 685 (1980) (Rehnquist, J., concurring). It is the enactment of § 2946(5), and not the FDA findings it incorporates, that involves the allocation of societal rights and duties in the drug liability arena. It is the enactment of § 2946(5) through which the Legislature has balanced the competing interests, not the incorporation of an FDA finding.

Once it is recognized that the Michigan Legislature did not delegate legislative or policy decisions to the FDA, it follows that there is no need for the Michigan Legislature to retain "oversight" over the FDA to steer clear of the nondelegation doctrine. To the

extent that "oversight" of the federal agency is pertinent, the Michigan Legislature retains the ultimate oversight through its ability to continue, to amend, or to rescind § 2946(5).

When placed in this context, the authorities cited by the Michigan Court of Appeals panel are largely irrelevant to the delegation question. The Court of Appeals panel cites to Michigan cases for the proposition that the nondelegation doctrine is violated by the incorporation by reference of statutes established by sister states or by the federal government. The panel reasoned that such statutes may change in the future, and that the Michigan statutes already on the books would derivatively adopt such change in policy. Section 2946(5) is distinguishable. The Michigan Legislature did not adopt a statute or other policy decision made by a sister state or by the federal government when incorporating by reference an FDA scientific determination. Rather, § 2946(5) reflects the continued policy determination by the Michigan Legislature that recovery in such cases will be dependent on the scientific and medical judgments of government experts, and that lay jurors will not be allowed to second guess a standard that has been developed in excruciating detail by these government experts. Although the science underlying the FDA process may change and evolve, it does not alter the policy decision made up front by the Michigan Legislature to defer to that science. In fact, it enhances and fulfills the existing policy determination that state of the art science should govern the parameters of a civil liability action, especially in the area of pharmaceutical litigation, which is especially affected by mass tort type litigation (which experience has shown can be

devastating notwithstanding the medicine on the side of the defense (see, e.g., Bendictin, breast implants and, for that matter, phentermine[16])).

Case law supports Medeva's position. In *Michigan Baptist Home and Development Co v City of Ann Arbor,* 55 Mich App 725; 223 NW2d 324 (1974), the Michigan Court of Appeals recognized that reference to a federal standard does not delegate legislative power from the Michigan Legislature to the federal agency. In *Michigan Baptist Home*, the plaintiff claimed that the Michigan Legislature violated the nondelegation doctrine by incorporating by reference the category of "low-income housing" as an exemption to the General Property Tax Act. The appellate court disagreed, nothing that the federal official does not decide who receives the exemption, but merely crafts the category of exemption which the Michigan Legislature, in its wisdom, determined should have an exemption:

> "Plaintiff claims that the Michigan Legislature, by limiting the exemption provided by section 7d(1) of the General Property Tax Act . . . has made the exemption dependent upon actions by the Secretary of Housing and Urban Development, and that limiting the exemption in this manner is invalid as an unconstitutional delegation of power to a Federal official who decides who receives the exemption. We disagree.
>
> The Federal official does not make a determination as to who should receive the exemption. He merely determines which nonprofit corporations are eligible to receive Federal financing under § 202. Furthermore, this provision for Federal financing of housing for the elderly was no doubt created for the lowest income type of housing, since it is almost impossible to obtain sufficient financing for these projects from other sources. *In other words, our Legislature intended that the tax exempt status be extended to*

[16] To date, no court has found that there is reliable scientific evidence demonstrating that phentermine caused or contributed to the development of primary pulmonary hypertension or valvular heart disease.

> *the lowest income type of housing. The Legislature has merely created a special category of low-income housing for the elderly which is to be granted tax-exempt status.* We perceive neither discrimination nor any violation of either equal protection or due process in the creation of the special category of low-income elderly housing for exemption from taxation."

Michigan Baptist Home, supra, 55 Mich App at 737-738 (emphasis supplied).

In similar fashion, the Michigan Legislature decided through the enactment of § 2946(5) that science shall decide safety and efficacy of prescription drugs for purposes of civil drug liability litigation. Just as the director of HUD did not decide which level of income triggers an exemption from the General Property Tax Act, so too the FDA has not decided those drug liability cases in which lay jurors can second-guess a standard that has been developed by governmental experts.

The second principal flaw with the Court of Appeals panel's reasoning is the failure to distinguish between incorporation of policy decisions made by another body (such as a sister state or the federal government), and incorporation of matters of independent significance on a scientific level. In the former category, the delegate arguably involves itself in policy decisions which are more appropriate for the delegating body, here the Michigan Legislature. The latter situation presents itself in this case, by which a mere scientific determination made by governmental agency is the framework for implementing and effectuating the policy decision made up front by the Michigan Legislature. The Court of Appeals panel did not take into account that the alleged delegate, the FDA, will make only scientific and technical decisions which leave unaffected the legislative policy behind § 2946(5), namely to defer to the science.

The legislative use of independent significant standards does not violate the nondelegation doctrine. Various courts have held that there is no delegation at all where the standard adopted is independently significant of the adopting legislation. See, e.g., *Lucas v Maine Comm'r of Pharmacy*, 472 A2d 904 (Md 1984) (court finds adoption of a private entity's standards for accreditation of pharmaceuticals has aspect of significance beyond the state legislation which incorporates it for registering pharmacists in that state); *State v Wakeen*, 57 NW2d 364 (Wis 1953) (court holds that incorporation of the definition of "drug" as set forth in United States Pharmacopeia, or other related publications not a case of the delegation of legislative power because the compendia are published independent of the statute and not in response to it). See also *Michigan Baptist Home and Development Co v City of Ann Arbor, supra.*

This approach accords with practicality. Assuming, as it must, the Court honors the wisdom of the Legislative judgment to defer to the science in lieu of determinations by lay jurors unversed in such matters, the practicalities of implementing this policy (as opposed to delegating it) must be taken into account. Michigan does not have a body that analyzes the safety and efficacy of prescription drugs, let alone a body with the same resources as the FDA, which can implement the same vigorous and critical analysis. The Michigan Court of Appeals' reasoning would require the existence of such a state body or agency, the lack of which would doom the policy behind the legislation. In our increasingly complex society, replete with ever-changing and more technical problems, the Michigan Legislature therefore simply cannot do its job absent an ability to delegate

this scientific function under broad general directives. See, e.g., *Mistretta v United States*, 488 US 361, 372 (1989).

Third, and finally, the Michigan Court of Appeals panel's concern regarding the inability of the Michigan Legislature to check the exercise of a delegated power with respect to future decisions of the FDA doesn't apply to the facts presented against Medeva, which manufactured only phentermine. The FDA approved phentermine in 1959 as a short term appetite suppressant. Phentermine is now marketed under a number of brand names (thus explaining the existence of several phentermine Defendants in this lawsuit). All the decision making with respect to the safety and efficacy of phentermine in this capacity has already been considered and approved by the FDA, and the FDA has indicated no intent to alter its prior determination.

The very case law cited by the Michigan Court of Appeals supports Medeva's position on this point. For example, in *Redecki v Director of Bureau of Worker's Disability Compensation*, 208 Mich App 19; 526 NW2d 611 (1985), the Michigan Court of Appeals found objectionable an adoption by reference of future legislation enacted by another sovereign entity. The court concluded, however, that the effect of such a delegation was a presumption that the Michigan Legislature intended to "freeze the federal law as it was at the time of the original state statute." *Redecki, supra*, 208 Mich App at 24. See also *People v Urban*, 45 Mich App 255, 262-263; 206 NW2d 511 (1973).

If the Court "freezes" the FDA determination in effect at the time § 2946(5) was enacted, then phentermine is determined to be safe and efficacious, and there is no basis

for a drug liability action here (given Plaintiffs' concessions that the exceptions to the statute are inapplicable).

CONCLUSION

Plaintiffs have failed to demonstrate that § 2946(5) is a delegation of legislative power. The mere reference to a federal administrative agency's independent finding, which is used by the Legislature to define the parameters of a tort action, is not a delegation of legislative power.

Plaintiffs misunderstand the scope and intent of the nondelegation doctrine. The doctrine provides a limitation on the Legislature's power to delegate the power of legislation to others, including other branches of government and nongovernment. The reason for a prohibition is to prevent an unchecked delegation of power, which undercuts the Legislature's accountability to the electorate, and subjects the populous to rule through ad hoc commands, rather than democratically considered general laws. Here, the Michigan Legislature decided through the enactment of § 2946(5) the policy questions involved in the arena of drug liability. The legislative accountability remains. The Legislature decided what is and what is not permissible with respect to a money recovery in a drug liability action. The Legislature determined that the prior tort system stifled innovation, restricted the availability of goods and services, and reduced the competitiveness of Michigan businesses, leaving the "look of a lottery" though the then-governing tort system. The Legislature determined that it would be unfair to deem a product defective when it conforms to government standards, and that lay jurors should not be allowed to second guess a standard that has been developed by government experts. The legislative history shows an intent to defer to the science surrounding

prescription drugs, as verified through the FDA process. Here it is the Michigan Legislature – not the FDA – that decides what is permissible and what is impermissible for jury determination.

In short, it is the Legislature that has allocated the societal rights and duties in the drug liability arena by the very enactment of § 2946(5).

Assuming *arguendo* there is a delegation of legislative power, it is authorized by the delegation doctrine and is otherwise constitutional. "The legislature cannot delegate its power to make a law, but it can make a law to delegate a power to determine some fact or state of things upon which the law makes or intends to make its own action depend. To deny this would be to stop the wheels of government." *City of Detroit v Detroit Police Officers Ass'n*, 408 Mich 410, n 29; 294 NW2d 68 (1980), quoting with approval *Locke's Appeal*, 72 Pa 491, 498-499 (1873). This principle has survived over 125 years of our jurisprudence because it is fundamental to the proper exercise of government and is legally unassailable. The bedrock underlying the nondelegation doctrine will be forever altered if, as Plaintiffs implore, a legislative body is prohibited from incorporating by reference a decision made by another body. This result would be devastating to the establishment and enabling of legislation, especially in areas in which the subject matter is most efficiently and knowledgeably dealt with by experts, and in areas where there already exists a tradition of regulation by administrative agency (such as insurance, banking, and the FDA). If accepted, the Plaintiffs' position unduly and unnecessarily interferes with the Michigan Legislature's broad discretion in dealing with matters of public health, safety, and morals. The better course is to correctly recognize the limited

scope and application of the nondelegation doctrine, which in turn requires a finding that § 2946(5) is constitutional.

RELIEF

WHEREFORE Defendant-Appellant Medeva Pharmaceuticals, Inc. requests this Court hold that MCL 600.2946(5) is constitutional, reverse the Michigan Court of Appeals' decision, and remand to the lower courts for entry of orders consistent with this Court's opinion, together with any relief the Court determines appropriate, including the recovery of all costs and attorney fees sustained on appeal.

Respectfully submitted,

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Dated: August 26, 2002

PROOF OF SERVICE

STATE OF MICHIGAN)
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COUNTY OF OAKLAND)

Audra A. Arndt, being first duly sworn, deposes and says that she is an employee with the firm PLUNKETT & COONEY, P.C., and that on the 20th day of August, 2002, she caused to be served two copies of Defendant-Appellant Medeva Pharmaceuticals, Inc.'s Brief on Appeal, Appendix on Appeal, and Proof of Service upon the following:

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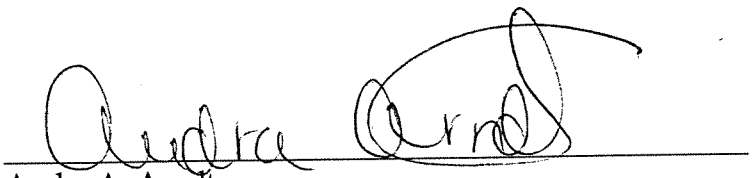
by enclosing same in pre-addressed, pre-stamped envelopes and depositing same in the United States Mail.



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